

**REMARKS**

**I. Support for the Amendments**

Amendments to the specification are provided in the Substitute Specification, marked and unmarked copies of which are filed herewith along with a Statement That the Specification Contains No New Matter.

In accordance with the Examiner's objection, the word "which" (originally on page 16, line 14) has been deleted as shown in the marked Substitute Specification. Other amendments reflect the amendments made during prosecution of the parent application (U.S.S.N. 09/354,664; now U.S. Patent 6,750,059), correct the spelling of "Hepes" to "HEPES", replace "FTA<sup>TM</sup>" with "FTA<sup>®</sup>", and add the number of the now-issued parent application. The substitute specification has been amended to include the previously submitted sequence listing, which was filed with the parent application (U.S.S.N. 09/354,664) on July 16, 1999, and which was previously included in the Preliminary Amendment filed with the present application. Support for the amendments to the specification can be found in the specification as filed and in the parent specification as filed. No new matter is added by virtue of the amendments to the specification.

Claims 1-32 were originally in the application. Claims 1-25 have been cancelled. Claims 26-39 were previously in the application.

New claims 40-44 have been added and claim 28 has been canceled. Claim 28 has been canceled without prejudice to its pursuit in an appropriate divisional or continuation application.

No new matter has been added by virtue of the amendments to the claims.

Support for new claims 40-44 can be found in the original specification, figures, and claims. Additional support for new claims 40-44 can be found, e.g., on page 3, lines 24-28; on page 6, lines 13-26; and in the Examples. Additional support for new claims 43-44 can be found, e.g., from page 1, line 19, to page 2, line 6; on page 3, lines 3-9; from page 6, line 27, to page 10, line 2; and in the Examples.

## **II. Status of the Claims**

Claims 1-32 were originally in the application. Claims 1-25 have been cancelled. Claims 26-32, which were previously non-elected claims in U.S.S.N. 09/354,664, were previously in the application.

Claims 26-32 were subject to a restriction requirement. Claims 26-28 were elected, and claims 33-39 were added.

Claims 26-27 and 33-44 are currently in the application. Claims 40-44 have been added in the present Amendment, and claim 28 has been canceled without prejudice.

## **III. The Information Disclosure Statement is Acknowledged**

Applicants thank the Examiner for acknowledging the Information Disclosure Statement.

#### **IV. The Power of Attorney**

The Examiner has stated that there is no power of attorney, but the present application is a divisional application, and the parent power of attorney should apply. The original Declaration & Power of Attorney in the parent application was filed by the inventors. A Revocation and Grant of Power of Attorney was subsequently executed and filed on 15 November 2001, prior to the filing of the present application.

Applicants respectfully request confirmation that no additional power of attorney is required.

#### **V. The Request for a Corrected Filing Receipt**

The Examiner notes that Applicants have requested a corrected filing receipt. Applicants have also filed new assignment and power of attorney documents in the present application and in the parent application. Applicants are currently awaiting a revised, corrected filing receipt.

#### **VI. The Drawings are Accepted**

The Examiner has accepted the drawings, but states that an artifact file created on 17 November 2003 seems to indicate that color drawings or color photographs were filed. Applicants wish to confirm that neither color drawings nor color photographs were filed in the present application. Applicants also note that the present application is a divisional application of U.S.S.N. 09/354,664 (now U.S. Patent 6,750,059).

## **VII. The Objection to the Specification**

The Examiner has objected to the specification “because of alterations which have not been initialed and/or dated as required...” and has requested a new oath or declaration. Applicants traverse this requirement, as the present application is a divisional application.

The only alteration found is the addition of the word “which” on page 16, line 14. It is noted that the addition of the word “which” does not alter the scope of the present application.

On 28 September 2006, Applicants’ undersigned representative telephoned the Examiner regarding this objection. In the course of the telephone interview, the Examiner agreed that the word “which” added no new matter and suggested that Applicants amend the paragraph to delete it, stating that there would be no need to submit a replacement oath or declaration. Applicants have amended the specification in accordance with the Examiner’s instructions and respectfully submit that the objection is rendered moot.

## **VIII. The Rejection of Claims 26-28 and 33-39 under 35 U.S.C. §103(a) is Traversed**

The Examiner has rejected claims 26-28 and 33-39 under 35 U.S.C. § 103(a), alleging obviousness over Rogers et al. (Analyt. Biochem. 247: 223-227 [May 1997]; “Rogers & Burgoyne” or “Rogers”) in view of Burgoyne (U.S. Patent 5,496,562) in view of Kahn et al. (Methods Enzymol. 68: 268-280 [1979]; “Kahn”). Applicants respectfully traverse this rejection.

The Patent Office alleges, in part:

The claims are drawn to a method of isolation of vectors from host cells by contacting the host cells with a solid medium. In some embodiments the solid medium protects the vector from degradation, is made of cellulose or a micromesh plastic, the host cells are in solution, and the solid medium comprises urate salt, a chelating agent, and an anionic detergent.

Rogers et al. shows in the abstract and throughout recovery of DNA from bacterial liquid cultures by application of the bacterial culture to FTA blood storage medium. Figures 1 and 2 show positive results of PCR assay of bacterial DNA from FTA media to which bacterial cultures were applied. Rogers et al. shows that the DNA is stable for at least 1.6 years after application to the FTA media on page 226. Rogers et al. does not show use of bacteria comprising vectors, media comprising micromesh plastic, and Rogers et al. does not detail the composition of the chemicals in the FTA media. Rogers et al. states on page 223 that FTA medium is described in Burgoyne (U.S. Patent No. 5,496,562).

Burgoyne shows the components of a solid medium for preserving DNA in columns 2-4, including use of a solid support such as cellulose or a micromesh of a synthetic plastic (column 2, lines 21-23), urate, an anionic detergent, and a chelating agent (column 2, lines 54-64 and column 3, lines 18-26). Burgoyne shows storage of plasmids on the solid medium in column 4, line 61.

Kahn et al. reviews plasmid cloning vectors, and shows that such vectors are replicated in bacteria in the abstract and throughout. Kahn et al. shows on page 268 that plasmid vectors are useful for cloning and maintenance of foreign DNA.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Rogers et al. by use of bacteria comprising vectors because Burgoyne shows that the solid media used by Rogers et al. can be used for long term storage of plasmids, and Kahn et al. shows that bacterial plasmid vectors are useful for cloning and maintenance of foreign DNA. [Pp. 5-6; par. 10; all emphasis added.]

Applicants respectfully disagree.

Independent claim 26 reads as follows:

26 (currently amended). A method of isolating or purifying one or more vectors from a host cell or virus comprising:

- a) contacting a matrix or solid medium with a sample comprising a host cell or virus containing said vector or vectors; and
- b) isolating all or a portion of said vector or vectors from said medium.

[Emphasis added.]

First, Rogers studied polymerase chain reaction (PCR) amplification of genomic DNA *in situ* on FTA<sup>®</sup> medium. In contrast, the present application demonstrates the ability of plasmid DNA to elute from the washed punch after a 20-minute incubation in buffer at room temperature such that the plasmid vector DNA is isolated from the FTA<sup>®</sup> medium (e.g., p. 13, ll. 3-6), in accordance with claim 26.

Rogers neither teaches nor suggests the isolation/purification method of the present invention.

Nor are the deficiencies of Rogers remedied by the disclosure of Burgoyne. The application states that Burgoyne's patent 5,496,562 does apply plasmid DNA to FTA<sup>®</sup> cards and that the DNA is protected. However in Burgoyne's patent, previously purified plasmid DNA was applied to the FTA<sup>®</sup> cards and then the card was coated with a plastic polymer (polystyrene) to keep the card dry and/or preserve the DNA when stored in the freezer (Example 2). (Example 1 describes the use of detergent-aided proteolysis and phenol extraction to extract stored genomic DNA, while Example 3 describes in situ PCR amplification of genomic DNA.)

In the present application, two different host cells, bacteria and yeast, each containing plasmid DNA were applied to FTA<sup>®</sup> cards. The specification shows that the cells were lysed and the plasmid DNA retained and protected by the FTA<sup>®</sup> chemicals during room temperature storage (for at least 3 months; p. 18, ll. 28-29). M13 plaques and cells infected with M13 bacteriophage were also used (see Example 4). As shown in Examples 1-2, plasmid DNA directly from host cells can be eluted by washing in order to isolate it from the FTA<sup>®</sup> card (see, e.g., p. 17, ll. 1-17 and Table 4; p. 13, ll. 3-6; p. 14, ll. 16-18 and 25-30).

One of ordinary skill in the art would not have been motivated to combine the teachings of Burgoyne with those of Rogers. Genomic DNA, due to its large size relative to plasmid DNA,

behaves differently under various circumstances. Differences in the properties of genomic vs. plasmid DNA have been exploited in a wide range of laboratory processes, e.g., in DNA isolation in order to separate the two types of DNA (see, e.g., Old & Primrose, Principles of Gene Manipulation (4<sup>th</sup> ed.), Blackwell Scientific Publications [Boston: 1989]).

For example, it has been shown that plasmid DNA significantly elutes from a punch. The Examiner's attention is directed to Hansen & Blakesley, "Simple Archiving of Bacterial and Plasmid DNAs for Future Use," Focus 20(3): 72-74 (1998), a copy of which is enclosed for the Examiner's convenience:

However, the amount of plasmid DNA remaining with the paper is probably low. Standard fluorescent cycle sequencing of plasmid DNA directly from a washed punch did not detect any signal... [P. 74, c. 1.]

Similarly, Kahn's disclosure, e.g., that bacteria can contain plasmid cloning vehicles, fails to remedy the deficiencies of Burgoyne and/or Rogers.

In view of the foregoing, Applicants respectfully submit that claims 26-28 and 33-39 fulfill the requirements of 35 U.S.C. §103(a), and request the Examiner's reconsideration of these claims accordingly.

**CONCLUSION**


In view of the foregoing amendments and remarks, the present application is respectfully considered in condition for allowance. An early reconsideration and notice of allowance are earnestly solicited.

It is believed that all outstanding rejections have been addressed by this submission and that all the claims are in condition for allowance. If discussion of any amendment or remark made herein would advance this important case to allowance, the Examiner is invited to call the undersigned as soon as convenient.

Applicants hereby request a three-month extension of time for the Amendment and accompanying materials. If, however, a petition for an additional extension of time is required, then the Examiner is requested to treat this as a conditional petition for an extension of time and the Commissioner is hereby authorized to charge our deposit account no. 04-1105 for the appropriate fee. Although it is not believed that any additional fee (in addition to the fee concurrently submitted) is required to consider this submission, the Commissioner is hereby authorized to charge our deposit account no. 04-1105 should any fee be deemed necessary.

Respectfully submitted,

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